

**REMARKS/ARGUMENTS**

**I. Status of the Claims**

After entry of this amendment, Claims 107 and 108 are pending. Claims 1-4, 6, 8, 10-17, 19-36, 38, 40, 42-49, 51, 52, 54, 55, 87-89, 91, 93, 95-102 and 104 are cancelled. Claims 107 and 108 are new. Support for new Claim 107 and 108 can be found in the claims as originally filed and throughout the specification, for example, original Claim 1 and in the specification on page 27, lines 3-4.

**II. Responses to the Rejections**

***Over 35 U.S.C. §112, first paragraph, enablement***

Claims 1-4, 6, 8, 10-17, 19-21, 31-36, 38, 40, 42-49, 51, 54-55, 87-89, 91, 93, 95-102, and 104 are rejected under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. Claims 1-4, 6, 8, 10-17, 19-21, 31-36, 38, 40, 42-49, 51, 54-55, 87-89, 91, 93, 95-102, and 104 are cancelled and new Claim 107 has been presented. In view of the amendments to the claims, the Applicants respectfully request that this rejection be withdrawn.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Furthermore, a patent need not teach, and preferably omits, what is well known in the art. *In re Butcher*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991; *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). See also, MPEP § 2164.01. Also, the presence of inoperative embodiments within the scope of a claim does not necessarily render a claim not enabled. The standard is whether a skilled person could determine which embodiments that were conceived, but yet made, would be inoperative or operative with expenditure of no more than is normal

required in the art. *Atlas Power Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 244 USPQ 409, 414 (Fed. Cir. 1984). *See also MPEP § 2164.08.*

In the spirit of expediting prosecution, Applicants have cancelled the previously pending claims and have presented new Claim 107, which recites that the fucosylation is performed by a recombinant eukaryotic FucT-VI or FucT-VII fucosyltransferase. The efficacy of the claimed methods involving these two classes of fucosyltransferases have been experimentally demonstrated and are supported by the specification. Moreover, the Office Action agrees that the present specification enables a method a using recombinant eukaryotic FucT-VI or FucT-VII fucosyltransferase to modify the glycosylation pattern of a glycopeptide (See Office Action, page 3, first paragraph).

The Applicants note that the specification provides ample disclosure to enable one skilled in the art to practice the claimed invention. For example, FucT-VI and FucT-VII fucosyltransferases are described on pages 26-28; exemplary glycopeptide substrates that are suitable for modification according to the methods of the invention are described in general on pages 20-22, and in particular in Table 1 of page 21; suitable acceptor moieties for fucosyltransferase-catalyzed attachment of a fucose donor are described on pages 28 and 29; and suitable conditions for carrying out the methods of glycosylating a glycoprotein using a mutant endoglycanase of the invention are described on page 37-38. The specification also provides working examples (Examples 2 and 3) showing the results of the substrated specificity and fucosylation activity of the fucosyltransferases.

Moreover, methods of determining whether an intended FucT-VI or FucT-VII fucosyltransferase-mediated modification occurred are readily accessible to, and well within the abilities of, those of skill in the art. Representative examples of such methods are set forth in the specification. Methods of assessing fucosylation patterns of glycopeptides prepared using FucT-VI or FucT-VII fucosyltransferase of the invention are described on page 33, and see Example 4. Therefore, in view of the guidance provided in the specification, in combination with the knowledge of one of skill in the art, any experimentation that may be performed is reasonable in scope and cannot be properly characterized as “undue”.

In summary, the specification clearly teaches that FucT-VI or FucT-VII can be used *in vitro* to provide a substantially uniform fucosylation pattern for glycopeptides. The specification also provides ample examples to demonstrate the operability and success of the claimed methods achieved by following the teaching and guidance provided by the present invention. Therefore, the Applicants respectfully request that this rejection be withdrawn.

***Over 35 U.S.C. §112, first paragraph, written description***

Claims 1-4, 6, 8, 10-17, 19-21, 31-36, 38, 40, 42-49, 51-53, 66-68, 70-77, 79-86 and 94 are rejected under 35 U.S.C. § 112, first paragraph for alleged lack of written description. Applicants have amended the claims and therefore traverse this rejection.

In the spirit of expediting prosecution, Applicants have cancelled the previously pending claims and have presented new Claim 107, which recites that the fucosylation is performed by a recombinant eukaryotic FucT-VI or FucT-VII fucosyltransferase.

As noted above, the specification provides ample written description for use of a FucT-VI or FucT-VII fucosyltransferase in fucosylating a glycopeptide, including working examples (Examples 2 and 3) showing the results of the substrated specificity and fucosylation activity of the fucosyltransferases.

Accordingly, the Applicants respectfully submit that the claimed methods meet the written description requirements of 35 U.S.C. § 112, first paragraph. Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Applicants respectfully request a telephone interview if the Examiner believes that the claims as amended are not in condition for allowance in light of the response submitted above. The undersigned can be reached at 415-442-1000.

Respectfully submitted,



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